In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

JERILYN GREENHAW,	*	No. 21-2032V
Petitioner,	*	Special Master Christian J. Moran
v.	*	Filed: January 2, 2024
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Bradley S. Freedberg, Denver, CO, for petitioner;
Benjamin Patrick Warder, United States Dep't of Justice, Washington, DC, for respondent.

DECISION DENYING ENTITLEMENT TO COMPENSATION[1]

Jerilyn Greenhaw alleged that the influenza ("flu") vaccine caused her to suffer from small fiber neuropathy ("SFN"), oropharyngeal dysphagia, gastric dysmotility, and degenerative disease of the nervous system. Am. Pet., filed Apr. 4, 2022. The Secretary disputed this allegation, contending that Ms. Greenhaw did not have a comprehensive diagnosis that explained her various complaints and that many of her symptoms predated the administration of her flu vaccine. Resp't's Rep., filed June 6, 2022. The Secretary contested that Ms. Greenhaw failed to prove that there is a causal link between the flu vaccination and her conditions. Id.

[1] Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

Ms. Greenhaw has not presented evidence to fulfill her burden of proof, despite presenting four reports from a doctor. She has not established with preponderant evidence a theory by which the flu vaccine can cause her conditions. She is not entitled to compensation. Thus, her case is DENIED.

I. Background Material[2]

Ms. Greenhaw presented information about her health via two methods, medical records and affidavits. These are discussed below.

A. Medical Records

Ms. Greenhaw was born in 1977. Before her vaccination, significant medical problems included sleep apnea, gastroesophageal reflux disease ("GERD"), anxiety, depression, insomnia, and perioral dermatitis. Exhibit 15 at 1-2; Exhibit 10 at 303, 307. She tested positive for anti-nuclear antibodies ("ANA"). Exhibit 10 at 293.

Ms. Greenhaw was 41 years old when she received the flu vaccine on October 2, 2018. In November 2018, she reported to a medical assistant, Cynthia Cantu, that "she has been noticing some changes such as memory loss and short term memory [and] that she is starting to stutter within the past 6 months." Exhibit 2 at 1. Ms. Greenhaw saw a physician assistant, Erin Villela to whom she complained of "several months of bodyaches from her shoulders/arms and lower back [and] having difficulty with word finding." Exhibit 10 at 313. She reported that her gait had changed, causing her to trip often and that she was seeking treatment from a rheumatologist for mixed connective tissue disease. Id. The physical examination did not reveal any abnormality with sensation and gait. Id. at 316. Ms. Villela ordered an MRI of her brain, refilled her Xanax prescription, and discussed the need for sleep. Id. at 317. Ms. Greenhaw also expressed her concerns to a nurse, Sharon Artman, stating that approximately 6 months ago, she had started to experience strange symptoms, including "tripping over [her] right leg," difficulty with expressing her thoughts, "mix[ing] up words," repeating herself, memory problems, problems with hand-eye coordination, difficulty writing the letters of the alphabet, muscle twitches and tics in the legs and feet, and stabbing pelvic pains. Exhibit 2 at 1. In late November 2018, Ms. Greenhaw's lab

[2] The facts are presented summarily because this case is being resolved on an element of proof, the causal theory allegedly connecting the flu vaccine to Ms. Greenhaw's conditions. For more detailed accounts of the medical records, see Resp't's Rep., filed June 6, 2022.

testing for autoimmune disease showed the presence of ANA with a speckled pattern. Exhibit 10 at 325. The MRI showed "minor nonspecific hemispheric leukoencephalopathy with mild changes in the pons." Exhibit 1 at 33. There was no evidence of an acute abnormality or mass effect. Id.

In December 2018, Ms. Greenhaw saw a neurologist, Dr. Walter Werchan, and a rheumatologist, Dr. Sonia Yousuf. Dr. Werchan noted Ms. Greenhaw's complaints, including an unsteady gait, tripping over her feet, dropping things, memory loss, cramps in her hands and feet, difficulty speaking, muscle twitches, difficulty finding words, memory issues, cramping in her hands and feet, pelvic pain, loss of appetite, tremors, ringing in her ears, urinary changes, pelvic pain, fatigue, itching, and jaw pain. Exhibit 3 at 6. She reported that she started having "right foot drop" in mid-November 2018 and "for the last 6 months, she has had 'mental fog' with difficulty thinking, mixing up words, repeating sentences, [and] short-term memory problems." Id. Dr. Werchan stated that her unsteady gait and problems with dropping things were of unclear etiology; however, he opined that these symptoms might be due to neuropathy, radiculopathy or myelopathy. Id. at 4. Dr. Werchan recommended her to have an MRI of the cervical spine and electrodiagnostic testing to identify the cause of her unsteady gait and problems with dropping things. Id.

Ms. Greenhaw presented to Dr. Yousuf for a one-year follow-up appointment for widespread myalgias and positive ANA. Exhibit 2 at 3. Dr. Yousuf wrote that she initially developed symptoms of Raynaud syndrome in February 2017 and attributed her myalgias to fibromyalgia. Id. at 6. Dr. Yousuf reviewed her repeat ANA results (1:40 with speckled and homogenous pattern) and opined that there was "no convincing evidence of connective tissue disease besides Raynauds and ANA is low titer positive." Id.

In January 2019, Ms. Greenhaw underwent MRIs of her lumbar and cervical spine. Although the lumbar spine MRI revealed spinal canal narrowing at the L4-L5 vertebrae, there was no localized neural impingement. Exhibit 1 at 17. The cervical spine MRI did not reveal any signal abnormalities, but it showed spondylosis of the C6-C7 vertebrae producing moderate left foraminal and mild spinal canal stenosis. Id. at 19.

Several months later, in June 2019, Dr. Werchan suspected the diagnosis of small fiber neuropathy. At this appointment, Dr. Werchan reviewed Ms. Greenhaw's past medical history and noted: "She . . . has intermittent itching in hands and feet and feels it is neuropathic . . . [S]he continues with 'drop foot' and

dragging her feet at times . . . She also has [a] new complaint of tremor intermittent in bilateral upper [extremities], nothing improves or worsens." Exhibit 27 at 172. Based on these reported symptoms, Dr. Werchan referred her to a neurologist, Dr. Yessar Hussain, to further examine her. Id. at 169.

About two months later, in August 2019, Ms. Greenhaw presented to Dr. Hussain. Exhibit 12 at 5. Ms. Greenhaw reported that she first noticed her symptoms in late 2018, which included dragging her feet, a clumsy grip, brain fogginess. Id. She explained that her "symptoms progressed and started having sensory symptoms too, on and off, diffuse, including her lower and upper extremities [and] [t]hen started having muscle fasciculation at [lower extremities], no triggers, and cramps at hands and feet." Id. Ms. Greenhaw's report of these symptoms prompted Dr. Hussain to order a skin biopsy for evaluation of small fiber neuropathy. Id. at 7. The results of the skin biopsy, collected on September 23, 2019, confirmed a diagnosis of small fiber neuropathy. Id. at 8.

From 2019 to 2021, the medical records show that Ms. Greenhaw continued to suffer from various symptoms. In addition to small fiber neuropathy, notable diagnoses included GERD (Exhibit 10 at 212), dysphagia (Exhibit 10 at 212), myalgia (Exhibit 2 at 11), pontine lesion (Exhibit 11 at 2), Sjogren's syndrome (Exhibit 6 at 9) and degenerative disease of the nervous system (Exhibit 6 at 9).

B. Affidavits

Ms. Greenhaw presented three affidavits to document her health before and after the vaccine. In the damages affidavit, she stated that before the vaccination, she was able to enjoy life with her family members, dine out at restaurants, hike and shoot guns at the shooting range. Exhibit 18. She explained that the "acute severe wide-ranging array of symptoms" due to the vaccine strained her relationship with her family members and made it difficult to eat, hike, and shoot at the shooting range. Id. She did not think the vaccination was beneficial for her health. Id. at 6. She believed that the vaccine caused her to suffer from a slew of neurological deficits, such as difficulty finding words and speaking in sentences and tripping over her feet when walking, and various medical issues, such as swallowing without aspiration. Id. at 3.

In Ms. Greenhaw's affidavit regarding the timeline of events, she considered herself to be in relatively good health before the vaccination. Exhibit 25 at 1. She had some medical problems, including undifferentiated connective tissue disease, Raynaud's, some thinning of hair, general muscle aches, and chronic long-term

memory issues. Id. However, after the vaccination, she noticed that she exhibited strange symptoms, such as repeating herself, mixing up words, and difficulty expressing her thoughts. She first realized these symptoms on November 2, 2018, exactly a month after her vaccination on October 2, 2018. Id. Later that month, she had an episode where she tripped over her foot 7 times in 15 minutes at work and an incident during which she was so light-headed that she "felt like [she] was not even inside [her] body . . . [and her] head was floating somewhere . . ." Id. at 2. When she showered, she felt "extremely short of breath [and her] legs and arms got very shaky." Id. at 2. She had stabbing pains all over her body and eventually saw a neurologist, Dr. Werchan, who said she likely had "peripheral neuropathy." Id. at 3. She wrote that her labs confirmed that she had small fiber neuropathy. Id. at 4.

In Ms. Greenhaw's onset affidavit, she clarified that she did not have the following problems in May 2018: tripping over her feet, difficulty expressing herself, mixing up words, repeating herself, memory loss, eye-hand coordination, writing letters, muscle twitches, and stabbing pelvic pain. Exhibit 28. She noted that she started to develop these symptoms 10 days after the flu shot and was "unsure of the exact date but can say with certainty that they were present in early November." Id. at 2. The symptoms began slowly but "hit like a wall in mid November." Id.

II. Procedural History

Ms. Greenhaw, appearing as *pro se*, initiated a claim in the National Vaccine Injury Compensation Program by filing a petition on October 18, 2021. She alleged that she suffered from various injuries, including small fiber neuropathy, leukoencephalopathy, and myositis as a result of receiving the flu vaccine on October 2, 2018.

In November 2021, she retained an attorney, Mr. Bradley Freedberg, to represent her. With his assistance, she filed medical records and confirmed that the record was complete on January 14, 2022. This statement of completion was subsequently amended on February 23, 2022.

The case was reassigned to the undersigned on February 4, 2022. A status conference was held on March 2, 2022 to discuss the next steps in the case. Since Ms. Greenhaw retained counsel, the undersigned suggested she submit an amended petition, which she did on April 4, 2022. In the amended petition, she alleged that

the flu vaccine caused her to suffer from small fiber neuropathy, oropharyngeal dysphagia, gastric dysmotility, and degenerative disease of the nervous system.

After reviewing the records, the Secretary contended that the medical evidence did not support Ms. Greenhaw's allegation and recommended that compensation be denied. Resp't's Rep., filed June 6, 2022. Specifically, the Secretary argued that she did not have a comprehensive diagnosis that explained her various complaints and that many of her symptoms predated the administration of her flu vaccine. Therefore, the undersigned issued an order to direct Ms. Greenhaw to answer specific questions regarding her medical records and the onset of her symptoms. Order, issued July 6, 2022. She filed the onset affidavit on September 30, 2022.

Once the record was largely complete, the undersigned proposed a set of instructions to facilitate the process of presenting expert reports and solicited comments. Order, issued Oct. 25, 2022. Ms. Greenhaw suggested slight changes. Pet'r's Resp., filed Nov. 8, 2022. Ms. Greenhaw's proposal was accepted and the Expert Instructions were made final on November 10, 2022.

Ms. Greenhaw was required to submit an expert report by January 23, 2023. Ms. Greenhaw sought for, and was granted, three extensions of time to file this expert report. On May 12, 2023, she filed a report from a doctor she retained in this litigation, Gurney Pearsall. Exhibit 34. This report is eight pages and does not cite any medical articles.

Dr. Pearsall opined "the flu vaccine administered on October 2, 2018, unequivocally triggered her small fiber neuropathy and its distressing symptoms." Id. at 8. Dr. Pearsall did not assert that the vaccination caused her to suffer other problems alleged in the amended petition, such as oropharyngeal dysphagia, gastric dysmotility, and degenerative disease of the nervous system. Consequently, the remainder of this decision focuses on the condition that Ms. Greenhall's expert has advanced with the most clarity---small fiber neuropathy.

A status conference was held on June 1, 2023 during which the undersigned stated that Dr. Pearsall's expert report did not comprehensively address the issues in respondent's Rule 4(c) report, particularly with regard to the disputed diagnosis that it could be something other than small fiber neuropathy. Order, issued June 2, 2, 2023. Dr. Pearsall's discussion of molecular mimicry was cursory. Id. The undersigned, therefore, required Ms. Greenhaw to submit an amended expert report from Dr. Pearsall.

Ms. Greenhaw filed an amended expert report on July 10, 2023. Exhibit 41. This report is two pages with a third page, listing two medical articles about cognitive impairments in patients with chronic pain. Id.

This report remained inadequate on the topic of causation. The undersigned ordered petitioner to show cause on why the case should not be dismissed due to the ineffective expert reports. The undersigned expressed that "[p]etitioner has not carried her burden of presenting a minimally persuasive case that the flu vaccination caused her conditions." Order to Show Cause, issued July 26, 2023. While Dr. Pearsall explained how the theory of molecular mimicry generally applies to vaccine cases, he did not specifically apply it to the facts in Ms. Greenhaw's case. Id.

Ms. Greenhaw responded to the show cause order by filing a second amended expert report on August 1, 2023. Exhibit 44. That expert report was, once again, insufficient because Dr. Pearsall had ruled out alternative causes of petitioner's condition(s) and primarily relied on the theory of molecular mimicry to explain that the flu vaccine caused petitioner's injuries. The undersigned emphasized that the Federal Circuit required more than a "mere showing of a proximate temporal relationship between vaccine and injury" to satisfy Ms. Greenhaw's burden. Ms. Greenhaw was afforded one last opportunity to submit a revised expert report to discuss molecular mimicry.

Ms. Greenhaw filed a third amended expert report on August 21, 2023. Exhibit 47. Petitioner's counsel followed up with a status report in September 2023, explaining that the undersigned's request is "impossible to comply with and that the medical records indicate that her immunization more likely than not catalyzed her sequence of symptoms." Petitioner's counsel urged the undersigned to permit the case to proceed with the existing expert reports. He pointed out that there have been "numerous VICP claimants [who] have proven entitlement in claims involving small fiber neuropathy." Pet'r's Status Rep., filed Sept. 13, 2023.

The undersigned has not ordered respondent to present expert reports. For the reasons explained below, this case will not advance further.

III. Standards of Adjudication

A. Burden of Proof

A petitioner is required to establish his case by a preponderance of the evidence. 42 U.S.C. § 300aa-13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing a special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with the dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

B. Elements of Proof

When pursuing an off-Table injury, a petitioner bears a burden "to show by preponderant evidence that the vaccination brought about [the vaccinee's] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Because special masters are often called upon to evaluate the persuasiveness of the theory of molecular mimicry, the Court of Federal Claims and the Court of Appeals for the Federal Circuit have considered molecular mimicry in their appellate role opinions from special masters. In December 2019, the undersigned identified the leading precedents as W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d 1352 (Fed. Cir. 2013), and Caves v. Sec'y of Dep't. of Health & Hum. Servs., 100 Fed. Cl. 119 (2011), aff'd sub nom., 463 F. App'x 932 (Fed. Cir. 2012). Tullio v. Sec'y of Health & Hum. Servs., No. 15-51V, 2019 WL 7580149, at *12-

14 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), mot. for rev. denied, 149 Fed. Cl. 448 (2020). While Tullio describes those cases in more detail, their essence appears to be that although molecular mimicry is accepted in some contexts, special masters may properly require some empirical evidence to show that a particular vaccine can cause a particular disease.

In the next approximately three years, appellate authorities reviewing decisions involving molecular mimicry have generally endorsed the approach of looking for some evidence that persuasively shows that a portion of a vaccine resembles a portion of human tissue, which contributes to causing the disease, and that the immune system will respond to the relevant amino acid sequence. Chronologically, the list of more recent appellate cases begins with the opinion in Tullio, which denied the motion for review. 149 Fed. Cl. 448, 467-68 (2020).

Another example in which the Court of Federal Claims held that the special master did not elevate the petitioner's burden of proof in the context of evaluating the theory of molecular mimicry is Morgan v. Sec'y of Health & Hum. Servs., 148 Fed. Cl. 454, 476-77 (2020), aff'd in non-precedential opinion, 850 F. App'x 775 (Fed. Cir. 2021). In Morgan, the Chief Special Master found that petitioner had not presented persuasive evidence about a relevant antibody. Id. at 477. The Chief Special Master also noted that the articles about the relevant disease do not list the wild flu virus as potentially causing the disease. Id. When examining this analysis, the Court of Federal Claims concluded: "the Chief Special Master did not raise the burden of causation in this case; petitioner simply failed to meet it." Id.

The Federal Circuit also evaluated the Chief Special Master's approach in Morgan. The Federal Circuit concluded: "We discern no error in the special master's causation analysis." 850 F. App'x 775, 784 (Fed. Cir. 2021).

Most other recent appellate cases follow this path. See, e.g., Duncan v. Sec'y of Health & Hum. Servs., 153 Fed. Cl. 642, 661 (2021) (finding the special master did not err in rejecting a bare assertion of molecular mimicry); Caredio v. Sec'y of Health & Hum. Servs., No. 17-79V, 2021 WL 6058835, at *11 (Fed. Cl. Dec. 3, 2021) (indicating that a special master did not err in requiring more than homology and citing Tullio); Yalacki v. Sec'y of Health & Hum. Servs., 146 Fed. Cl. 80, 91-92 (2019) (ruling that a special master did not err in looking for reliable evidence to support molecular mimicry as a theory); Dennington v. Sec'y of Health & Hum. Servs., 167 Fed. Cl. 640, 653-54 (2023) (discussing that a special master did not err in requiring more information on how molecular mimicry applies to petitioner's case), appeal docketed, No. 2024-1214 (Fed. Cir. Dec. 1, 2023); but

see Patton v. Sec'y of Health & Hum. Servs., 157 Fed. Cl. 159, 169 (2021) (finding that a special master erred in requiring petitioner submit a study to establish medical theory causally connecting flu vaccine to brachial neuritis).

C. Procedures for Evaluating Evidence

As inquisitorial judicial offers, special masters have been afforded broad authority to seek information. Congress stated special masters

> (1) may require such evidence as may be reasonable and necessary,
>
> (2) may require the submission of such information as may be reasonable and necessary,
>
> (3) may require the testimony of any person and the production of any documents as may be reasonable and necessary.

42 U.S.C. § 300aa–12(d)(3)(B). This discretion, however, is also limited by other procedural rules. See Simanski v. Sec'y of Health & Hum. Servs., 671 F.3d 1368, 1380 (Fed. Cir. 2012).

A special master's engagement in the presentation of evidence advances the goal of quicker litigation. "One reason that proceedings are more expeditious in the hands of special masters is that the special masters have the expertise and experience to know the type of information that is most probative of a claim." Doe v. Sec'y of Health & Hum. Servs., 76 Fed. Cl. 328, 338–39 (2007). A special master's requesting information can "mean[] he did his job." Id. at 339.

After special masters receive evidence, they may comment upon the persuasiveness of the evidence. See Vaccine Rule 5(a) (allowing special masters to "evaluate the parties' respective positions" and to "present tentative findings"). When a review of the evidence reveals that a petitioner's expert report is inadequate, special masters may resolve the case without requiring the Secretary to submit rebuttal evidence or to file a motion for summary judgment. Duncan v. Sec'y of Health & Hum. Servs., 153 Fed. Cl. 642, 656-57 (2021); see also Deidrich v. Sec'y of Health & Hum. Servs., 137 Fed. Cl. 51 (2018); Hayman v. United

States, No. 02-725, 2005 WL 6124101 (May 9, 2005).[3] Before special masters resolve a case without holding a hearing, special masters must allow the losing party an opportunity to present its case. Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2020) (recognizing that a special master may decide a case on written submissions without a motion for summary judgment); Duncan, 153 Fed. Cl at 657-58 (citing Kreizenbeck).

IV. Analysis

Ms. Greenhaw's case presents two questions, one procedural and the other evidentiary. The first question is whether Ms. Greenhaw has been given a fair opportunity to present her evidence. The answer is yes. The second question is whether the evidence Ms. Greenhaw has presented carries her burden of proof. The answer is no. Thus, Ms. Greenhaw's case is dismissed.

A. Fair Opportunity to Present Evidence

Multiple times Ms. Greenhaw was informed about the need to present evidence and was given chances to present the evidence. Mr. Freedberg, as an attorney who has represented other petitioners in the Vaccine Program, presumably came to the case with some background knowledge. Even in the absence of any general information, Ms. Greenhaw should have learned about her evidentiary burdens from the Secretary's report. See Simanski v. Sec'y of Health & Hum. Servs., 96 Fed. Cl. 588, 605 (2010) (noting that a purpose of the Rule 4 report is to alert all parties about the issues in the case), rev'd on other grounds, 671 F.3d 1368 (Fed. Cir. 2012). Here, the Secretary advised Ms. Greenhaw that her medical records do not meet the Althen prongs and that she had not retained an expert to support her claim. Resp't's Rep. at 18.[4]

To assist in the production of a meaningful expert report, the undersigned proposed instructions, setting out the minimum expected content. Ms. Greenhaw thereafter proposed some changes to the instructions, which were accepted and made final on November 10, 2022.

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[3] Although the respondent in Hayman is identified in the caption as the "United States," the opinion resolves a motion for review filed after a special master's decision.

[4] Ms. Greenhaw has not argued that the medical records entitle her to compensation. Thus, her case rises or falls on the strength of the report of Dr. Pearsall.

About half a year later, Ms. Greenhaw submitted an initial expert report from Dr. Pearsall. Dr. Pearsall opined that the flu vaccine triggered small fiber neuropathy and minimally addressed molecular mimicry. The undersigned cautioned that such a cursory discussion of molecular mimicry would not help petitioner prevail on her claim and ordered Ms. Greenhaw to file an amended report. Order, issued June 2, 2023. Ms. Greenhaw presented an amended report on July 10, 2023, which was inadequate and prompted the undersigned to issue an order to show cause. Order to show cause, issued July 26, 2023. The undersigned advised petitioner's counsel to review Tullio v. Sec'y of Health & Human Servs., No. 15-51V, 2019 WL 7580149, at *13-14 (Fed. Cl. Spec. Mstr. Dec. 19, 2019) because that decision cites various cases discussing molecular mimicry. Id. Ms. Greenhaw subsequently filed a second amended expert report on August 1, 2023 in an attempt to discuss molecular mimicry more substantively. However, this report remained insufficient. The undersigned, again, afforded petitioner "one last opportunity" to submit an amended expert report. The undersigned reminded petitioner's counsel to examine the caselaw in Tullio when addressing the theory of molecular mimicry. Order, issued August 15, 2023.

Ms. Greenhaw submitted a third amended expert report on August 21, 2023. She advised that "it is impossible to comply with" the precedent set in Tullio. She relied on the medical records to "indicate that her immunization more likely than not catalyzed her sequence of symptoms." Pet'r's Status Rep., filed Sept. 13, 2023. This status report communicated that Ms. Greenhaw does not want to submit additional evidence.

B. Ms. Greenhaw Has Not Presented Evidence to Demonstrate a Reliable Medical Theory under *Althen* Prong 1

Ms. Greenhaw advanced the theory of molecular mimicry to explain how a flu vaccine could cause small fiber neuropathy. The undersigned provided much guidance on appellate authority regarding molecular mimicry and offered Ms. Greenhaw and Dr. Pearsall multiple opportunities to explain how the flu vaccine could cause SFN via molecular mimicry.

As a preliminary point, Dr. Pearsall's experience appears not to lend itself to presenting a persuasive report for Ms. Greenhaw. Dr. Pearsall has not had any experience treating patients with the diagnosis of post immunization neuropathy and/or its subcategory small fiber neuropathy in the past five years. Exhibit 34. He provided expert testimony in one case of vaccine-related transverse myelitis and one case of post immunization neuropathy. Id. His curriculum vitae does not

mention any academic or professional experience in vaccines or small fiber neuropathy. Exhibit 49 (curriculum vitae). Rather, he describes himself as specializing in the "fields of Orthomolecular & IV Chelation Medicine, Minimally Invasive Aesthetic Medicine, Stem Cell Medicine, General Surgery and Family Medicine." Id. at 1. As such, Dr. Pearsall's expertise appears to be in areas unrelated to vaccines and small fiber neuropathy. Extending the case is not likely to lead to an enhancement of Dr. Pearsall's qualifications.

Dr. Pearsall's initial expert report from May 12, 2023 barely discussed the theory of molecular mimicry. He quoted the definition of "molecular mimicry" from R. T. Damian: "the sharing of antigens between parasite and host." Exhibit 34 at 6. He stated that the theory "is considered the most common mechanism for the induction of autoimmunity by a foreign source." Id. He did not provide a substantive explanation on how the flu vaccine might lead to a cross-reaction with components of the nervous system leading to small fiber neuropathy.

Similarly, the subsequent (amended) expert reports contain cursory explanations on how molecular mimicry pertains to Ms. Greenhaw's case. The theory is discussed in a general context and is not applied to the unique facts of this case.

In the expert report from July 10, 2023, Dr. Pearsall wrote:

> The theory of molecular mimicry suggests that certain non-host (foreign) proteins can induce an immune response that cross-reacts with a host's self-antigens, leading to autoimmune disorders. In the context of vaccines, molecular mimicry refers to the resemblance between components of the vaccine and the body's own molecules, specifically those found in normal tissues.
>
> Autoimmune disorders occur when the immune system mistakenly targets and attacks healthy cells and tissues in the body. Vaccines, while designed to trigger an immune response against specific pathogens, are known to induce immune responses that recognize self-antigens due to molecular mimicry.
>
> In this case, one or more antigens present in the vaccine may has [sic] share structural similarities with self-antigens. When the petitioner's immune system encountered these antigens during vaccination, it generated an immune response that not only targeted the intended antigens but also cross-reacts with similar self-antigens. This cross-reactivity lead to an immune

> response against the petitioner's own tissues, causing her constellation of symptoms secondary to autoimmune reactions.

Exhibit 41 at 2.

In the second amended expert report from August 1, 2023, Dr. Pearsall provided a thorough description of molecular mimicry but did not substantively address why it applies to Ms. Greenhaw's case. Exhibit 44. In the third amended expert report from August 21, 2023, Dr. Pearsall acknowledged that "the Greenhaw case conspicuously lacks a molecular-level 'smoking gun'" and concluded that there is a "rational inference" that there is a "higher probability than not" that the immunization catalyzed her sequence of symptoms. Dr. Pearsall elaborated that "[w]hile the Molecular Mimicry theory expounds upon the mechanism through which this phenomenon might have unfolded, definitive evidence illustrating which molecule enacted what action and at what juncture remains absent." Exhibit 46.

Dr. Pearsall's expert reports are sparse and conclusory, as they do not substantively explain how the theory of molecular mimicry applies to Ms. Greenhaw's case. Since the existing expert reports are inadequate to carry Ms. Greenhaw's burden, the undersigned required her to submit additional reports to support her claim.

Ms. Greenhaw cited eight cases in which petitioners with small fiber neuropathy received compensation in the Vaccine Program. Pet'r's Status Rep. at 2 n.1., filed Sept. 13, 2023. However, these are settlements and settlements carry little, if any, evidentiary value. See Woods v. Sec'y of Health & Hum. Servs., 105 Fed. Cl. 148, 152-53 (2012). Reasoned opinions may influence an adjudication of cases; however, they do not dictate how a special master should rule. See Boatmon v. Sec'y of Health & Hum. Servs, 941 F.3d 1351, 1358 (Fed. Cir. 2019) ("[S]pecial masters are not required to distinguish non-binding decisions of other special masters.")

Ms. Greenhaw has not presented a reliable medical theory to explain how the flu vaccine can cause small fiber neuropathy. Without sufficiently developed proof on this element, she cannot be found entitled to compensation.

The weakness of Dr. Pearsall's reports, considered singularly or collectively, is readily apparent. With "accumulated expertise," special masters can identify can cases that are not likely to be successful. See Whitecotton v. Sec'y of Health &

Hum. Servs., 81 F.3d 1099, 1104 (Fed. Cir. 1996). While conceivably respondent could have been directed to obtain a report, such a process would simply consume limited resources. Given that Dr. Pearsall has not shore up his opinions in response to multiple orders, there is no reason to expect that Dr. Pearsall will write a stronger report in response to an expert whom the Secretary retains. Ms. Greenhaw has enjoyed more than sufficient opportunities to make her case. It is simply time for all concerned to devote their attentions to other cases.

V. Conclusion

For the foregoing reasons, Ms. Greenhaw has not presented sufficient evidence to show that the flu vaccine caused her to develop small fiber neuropathy. Accordingly, her claim for compensation is DENIED.

The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including the deadline, can be found in the Vaccine Rules, which are available on the website for the Court of Federal Claims.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master